

# EXHIBIT B2-B

dispensed drugs. However, there is no evidence whatsoever to support the conclusion that the Legislature intended to subsidize the pharmacists' profit indirectly through reliance on inflated published average wholesale prices instead of simply increasing the dispensing fee paid to the pharmacists.

Nor is defendants' argument relevant that the EPIC program receives Average Manufacturers' Prices, which are "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts." 42 U.S.C. § 1396r-8(k)(1); Exec. Law § 547-j(3)(b). (Unlike average wholesale price, Average Manufacturers' Price is a defined term of art. 42 U.S.C. § 1396r-8(k)(1). State law adopts the federal definition by reference. Exec. Law § 547-j(3)(b). Under a CMS guidance, the Average Manufacturers' Price is supposed to be net of nearly all price concessions.) The EPIC Program keeps Average Manufacturers' Prices confidential, and there is no evidence the Legislature has had access to them. (Affidavit of Stephen C. Abbott.)

Finally, defendants conjure a policy argument that excessive drug reimbursement payments were necessary to protect patients' access to community pharmacies out of retail pharmacists' objection to reducing reimbursement on pharmacist-dispensed drugs from 90 percent to 85 percent of average wholesale price and the Legislature's adoption of a 13 percent discount. This is quite a leap: retail pharmacists could be expected to object vehemently to any additional discounting of average wholesale price.

In her testimony before a joint hearing on the Governor's budget proposal, the Commissioner of Health placed the proposed additional five percent discount in its political context -- the need for the State to restrain spending in light of the State's crippling fiscal crisis caused by the September 11<sup>th</sup> terrorist attacks, Wall Street's decline and the bleak national economic picture. Joint Hearing of the Senate Finance Comm. and Assembly Ways and Means Comm. on Health, Medicaid & Aging (2003) (testimony of Antonia C. Novello, Commissioner, Department of Health). (Fire. Aff. Ex. 13.) When

the Legislature did not enact the full discount proposed by the Governor, the Governor cast the Legislature's failure to limit Medicaid spending for drugs as an example of the body's alleged fiscal irresponsibility, not a poor policy judgment. (Governor's Veto Message No. 2 concerning Assembly Bill No. 2106B (2003) on 13th page. (Fire. Aff. Ex. 12.) There is no evidence that the proposed additional five percent discount to average wholesale price or the final compromise at an additional three percent discount were the result of a policy judgment about Medicaid reimbursement methodology or access to community pharmacies. These proposed discounts were an attempt to save the State money in a time of falling tax revenue and limited budgets, and the final compromise embodied in the statute was the outcome of a political and fiscal battle in which Medicaid drug reimbursement was only a tiny component.

Defendants' improbable hypothesis that the New York Legislature intended and acquiesced to spending millions of dollars in programs meant to benefit the poor solely to hide increases in pharmacists' dispensing fees not surprisingly is without support.

### **POINT III**

#### **THE STATE HAS ADEQUATELY PLEADED A CLAIM UNDER EACH OF THE CAUSES OF ACTION CONTAINED IN THE COMPLAINTS**

##### **A. The Complaints State a Claim Under The New York Deceptive Trade Practices Act, GBL § 349.**

Defendants' contention that the Attorney General has failed to sufficiently plead a cause of action under GBL § 349 reflects a fundamental misunderstanding of the Attorney General's authority under GBL § 349 as well as the facts of this case.

GBL § 349 declares unlawful any "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state." GBL § 349(b) expressly authorizes the Attorney General to bring an action for injunctive relief and restitution of

moneys or property obtained directly or indirectly as a result of such deceptive practices. Thus, GBL § 349(b) provides:

Whenever the attorney general shall believe from evidence satisfactory to him that any person, firm, corporation or association or agent or employee thereof has engaged in or is about to engage in any of the acts or practices stated to be unlawful he may bring an action in the name and on behalf of the people of the state of New York to enjoin such unlawful acts or practices and to obtain restitution of any moneys or property obtained directly or indirectly by any such unlawful acts or practices.

As reflected in its statutory language, GBL § 349 was “intended to be broadly applicable, extending far beyond the reach of common law fraud.” *State of New York v. Feldman*, 210 F. Supp. 2d 294, 301 (S.D.N.Y. 2002). *See also Blue Cross & Blue Shield of N.J., Inc. v. Philip Morris, Inc.*, 178 F. Supp. 2d 198, 231 (E.D.N.Y. 2001) (“section 349 was designed as a broad, remedial statute to relax traditional barriers to common law fraud”), *aff’d in relevant part, reversed in part*, 344 F.3d 211 (2d Cir. 2003), *Gaidon v. Guardian Life Ins. Co. of Am.*, 94 N.Y.2d 330 (1999). The statute seeks to secure an “honest market place” where “trust,” and not deception, prevails. *Oswego Laborers’ Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 85 N.Y.2d 20, 25 (1995) (quoting Mem. of Governor Rockefeller, 1970 NY Legis Ann. at 472). The statute has thus been held to apply to “virtually all economic activity” and must be liberally construed in light of its remedial purposes. *Karlin v. IVF America, Inc.*, 93 N.Y.2d 282, 290 (1999).

The GBL “parallels the most aggressive [consumer protection] statutes enacted in the country.” *Blue Cross & Blue Shield*, 178 F. Supp. 2d at 232. *See generally* Robert E. Reyna, *State Little FTC Acts and Unfair Methods of Competition*, SB75 ALI-ABA 47, n.13 (1997); Joseph Thomas Moldovan, *New York Creates a Private Right of Action*, 48 Brook. L. Rev. 509, 559 (1982) (consumer protections created by the GBL exceed the boundaries of deceptive conduct proscribed in uniform acts).

Ignoring the broad reach of GBL § 349, defendants assert that the State has failed to make out a Section 349 cause of action on four grounds: 1) that defendants’ conduct was “not misleading;”

2) that the State did not plead and cannot show that the practices at issue were "consumer-oriented;" 3) that GBL § 349 does not allow the State to recover its own losses; and 4) that defendants "did not cause the alleged injuries." There is no support in either fact or law for these contentions.

**1. DEFENDANTS ENGAGED IN DECEPTIVE PRACTICES WITHIN THE MEANING OF GBL § 349**

In each of its complaints, the State alleges that defendants' reported average wholesale prices and wholesale acquisition costs, which defendants knew would be used to determine published average wholesale prices, are deceptive and misleading because they are grossly inflated and "bear[ ] no relationship either to the price middlemen pay or to the price physicians, other health care providers and pharmacists actually pay to purchase these drugs." (Compls. ¶ 22.) According to the complaints, defendants' reported "wholesale" prices do not represent or even approximate any actual price paid by or to wholesalers. Rather they are fictitious prices fabricated by defendants to maximize the providers' profits and increase defendants' sales to the inevitable injury of consumers and the State. (Compls. ¶¶ 15-38.)

It is well-established that misrepresenting or inflating prices is a materially deceptive business practice within the meaning of GBL § 349. *Federated Nationwide Wholesalers Service v. FTC*, 398 F.2d 253, 257 (2d Cir. 1968) (misrepresenting that seller was offering merchandise for sale at "wholesale," "low wholesale," and "lowest wholesale" prices was a deceptive practice);<sup>12</sup> *Banks v. Consumer Home Mortg., Inc.*, 2003 WL 21251584 (E.D.N.Y. Mar 28, 2003) (inducing plaintiffs to purchase property at an inflated price stated a claim for deceptive practices under GBL § 349); *Polonetsky v. Better Homes Depot, Inc.*, 97 N.Y.2d 46 (2001) (selling homes at inflated prices

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<sup>12</sup> GBL § 349 (along with GBL § 350) is modeled after section 5 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45. New York courts routinely look to the FTC Act's definitions of deceptive acts or practices in interpreting GBL §§ 349 and 350. *See Feldman*, 210 F. Supp. 2d at 302; *Oswego*, 85 N.Y.2d at 26; *State v. Colorado St. Christian Coll.*, 76 Misc. 2d 50, 53-56 (Sup. Ct. N.Y. Co. 1973); *see also* Moldovan, 48 Brook. L. Rev. at 520-523, 553.

constituted a deceptive practice under New York City's deceptive practices law); *Gaidon v. Guardian Life Ins. Co. of Am.*, 94 N.Y.2d 330 (1999) (misrepresenting the amount of premiums to be paid on life insurance policies stated a claim under GBL § 349).<sup>13</sup>

Although defendants openly admit the core allegation of the State's deceptive practices claim -- that defendants' reported average wholesale prices substantially exceed the actual acquisition costs of their drugs -- defendants assert that their conduct is not actionable as a deceptive practice because the government knew these prices to be false and thus was not actually deceived. (Def. Mem. 40 - 41.) In addition to misconstruing the plain meaning of and history surrounding the use of "average wholesale price" as a measure of reimbursement (*see* Point I.A. above), defendants' argument is predicated on a fundamental misunderstanding of the law governing deceptive and fraudulent business practices.

Defendants misstate the elements of a deceptive practices claim. The traditional elements of common law fraud are not applicable to these claims. Thus, proof of reliance and actual deception are immaterial to a claim under GBL § 349. *Gaidon v. Guardian Life Ins. Co. of Am.*, 94 N.Y.2d 330 (1999) (not necessary under the statute that a plaintiff establish defendant's intent to defraud or mislead"); *Oswego Laborers' Local 214 Pension Fund*, 85 N.Y.2d at 26 (GBL § 349 "does not require proof of justifiable reliance"); *State v. Condor Pontiac, Cadillac, Buick and GMC Trucks, Inc.*, 2003 WL 21649689 at \*4 (Sup. Ct. Greene Co. July 3, 2003) ("It is not necessary for petitioner to establish intent, actual deception or reliance . . .").

Defendants' contention that there was no statutory deception because the government made a "deliberate policy choice" to use the average wholesale price as the benchmark by which to reimburse providers for drugs is flawed for several other reasons. First, the State is not challenging the decision to

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<sup>13</sup> Defendants' reliance on *Zuckerman v. BMG Direct Mktg., Inc.*, 290 A.D.2d 330, 331 (1<sup>st</sup> Dep't 2002), the only case cited under GBL § 349 to support their claim that their drug price reporting was not misleading, is particularly misplaced, given the fact that in *Zuckerman*, unlike the instant matter, the price quoted was the actual price.

use average wholesale price as the measure of reimbursement but rather defendants' inflation of those prices. Second, as discussed above (Points I and II), the Medicare, Medicaid and EPIC statutes and their legislative and regulatory history indicate that Congress and the State of New York intended for the words "average wholesale price" to have their commonly understood meaning and that they were not giving drug manufacturers the unbridled freedom to set those prices at any level they wanted. To the extent that the federal government became increasingly aware of defendants' fraudulent manipulation of their reported wholesale prices, the continued use of a reimbursement system based on average wholesale prices while the government studied the extent of the problem and developed a comprehensive solution can by no means be read as an endorsement of defendants' gross exaggeration of those prices. *See generally Pharm. Indus. MDL*, 263 F. Supp. 2d at 187 (The fact that Congress has failed to disturb the widespread practice on the part of pharmaceutical companies of grossly overstating their AWP's cannot be read as a clear and manifest intention to grant immunity from state regulation of such fraudulent practices."); *see also In re: Lupron MDL*, 2003 WL 22839966, at \*15 ("I am not impressed with the argument that the failure of Congress to act more forcefully in making changes to what in some respects appears to be a flawed AWP reimbursement mechanism evidences any preemptive intent on its part." ).

Finally, even if the State was generally aware that price inflation existed, it did not know, and could not know, the amounts by which each drug was inflated. *See, e.g., Pharm. Indus. MDL*, 263 F. Supp 2d at 178-179 (demonstrating discrepancies in reported average wholesale prices and the actual average wholesale prices ranging from 29% to as much as 20,735%). The full scope and details of the price inflation lies solely within defendants' possession and will be brought to light as a result of this litigation.

**2. DEFENDANTS' ACTIONS HAVE HARMED THE PUBLIC AT LARGE AND THUS ARE "CONSUMER ORIENTED"**

Defendants' second contention -- that to assert a claim under GBL § 349, the State must prove not only that the deceptive conduct *affected* consumers but that it was *aimed* at consumers -- finds no support

whatsoever in the language, history or case law construing GBL § 349. As noted by the Court of Appeals in *Karlin v. IVF America*, 93 N.Y.2d at 291, GBL § 349 has long been one of the “powerful tools aiding the . . . efforts to combat fraud in the health care and medical services areas.” In keeping with the broad remedial scope of GBL § 349, the requirement that the conduct objected to be consumer oriented “has been construed liberally.” *Feldman*, 210 F. Supp. 2d at 301. A defendant engages in “consumer-oriented” activity if its actions cause any “consumer injury or *harm to the public interest*.” *Id.* quoting *Securitron Magnalock Corp. v. Schnabolk*, 65 F. 3d 256, 264 (2d Cir. 1995) (Emphasis supplied). A viable cause of action under § 349 is pleaded where, as here, the gravamen of the complaint is “consumer injury or harm to the public interest.” *Securitron*, 65 F. 3d at 264. “The critical question . . . is whether the matter affects the public interest in New York.” *Blue Cross and Blue Shield of New Jersey, Inc. v. Philip Morris USA, Inc.*, 344 F.3d 211, 218 (2d Cir. 2003) quoting *Securitron*, 65 F. 3d at 264.

While the statute does not provide relief for solitary wrongful acts between commercial entities, acts of deception affecting a broad group of individuals or the public at large clearly states a claim under GBL § 349. The deceptive marketing of medical services and products is the kind of “consumer oriented” conduct that falls squarely within the protection of the statute. Thus, as the Court of Appeals held in *Karlin*, 93 N.Y.2d at 293, the public dissemination of misleading medical information is “precisely the sort of consumer-oriented conduct that is targeted by GBL § 349 . . .” Similarly, claims alleging that Medicare Part B beneficiaries were charged more than permitted under Medicare were held to “clearly state an ‘impact on consumers at large’” for the purposes of stating a claim under GBL § 349. *Sterling v. Ackerman*, 244 A.D.2d 170 (1<sup>st</sup> Dep’t 1997).<sup>14</sup>

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<sup>14</sup>For other cases demonstrating the breadth of conduct that courts consider to affect the public interest and thus be “consumer oriented,” see *Am. Medical Assoc. v. United Healthcare Corp.*, 2001 WL 863561, at \*15 (S.D.N.Y. July 31, 2001) (denying motion to dismiss § 349 claim for repeated reduction of insurance benefits, where “[p]laintiffs’ allegations do not describe a practice unique to plaintiff or a ‘single shot transaction’”); *In re Methyl Tertiary Butyl Ether (“MTBE”) Prod. Liability Litig.*, 175 F. Supp. 2d 593, 631 (S.D.N.Y. 2001) (holding that defendants’ alleged contamination of wells owned by plaintiffs was “sufficiently consumer-



In fact, the conduct alleged in the complaints indisputably affects the public interest. As a result of defendants' misrepresentations, the State and consumers, including, in particular, the elderly and the catastrophically ill, pay artificially inflated sums for chemotherapy and other drugs, and doctors and other health care providers are improperly induced to prescribe defendants' drugs. These practices directly impact the quality of care provided and have caused thousands of individual New Yorkers, as well as New York taxpayers generally, millions of dollars in annual overpayments. Contrary to defendants' characterization, the increase in out-of-pocket costs to Medicare beneficiaries is the direct, not "incidental," consequence of defendants' inflation of reported prices.

None of the cases relied on by defendants support defendants' claim that GBL § 349 is inapplicable to the claims at issue here. In contrast to this action, which was brought by the Attorney General pursuant to his statutory authority to protect the public interest under GBL § 349(b), all the cases relied on by defendants in which the court dismissed a GBL § 349 claim were private suits in which the conduct objected to presented no harm to the public at large but rather involved purely commercial or private contract disputes and typically were "single-shot" transactions unique to the parties.<sup>15</sup> Moreover,

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oriented to state a claim under section 349"); *City of New York v. Coastal Oil New York, Inc.*, 1998 WL 82927, at \*7 (S.D.N.Y. Feb. 25, 1998) (holding that contract bidder's alleged "scheme" that "distorted the market for fuel oil" affected the "public at large, and plaintiffs in particular."); *Riordan v. Nationwide Mut. Fire Ins. Co.*, 756 F. Supp. 732, 739 (S.D.N.Y. 1990) (holding that insureds' allegations that insurer engaged in illegal claims settlement practices "set forth precisely such evidentiary allegations of injury to the public at large as are required to sustain their claim under the GBL.").

<sup>15</sup> See, e.g., *Genesco Entertainment v. Koch*, 593 F. Supp. 743 (S.D.N.Y. 1984) (suit by concert promoter against city arising out of negotiations to lease Shea stadium did not state a claim under GBL § 349); *New York Univ. v. Continental Ins. Co.*, 87 N.Y.2d 308, 321 (1995) (claim by university against its insurer concerning the scope of coverage of a policy expressly tailored to meet the university's wishes and requirements was not consumer-oriented conduct under § 349); *P. Kaufmann, Inc. v. Americraft Fabrics, Inc.*, 232 F. Supp. 2d 220 (S.D.N.Y. 2002) (suit between competitors of upholstery fabric involving trademark infringement did not state a claim under GBL § 349); *Banc of Am. Commer. Fin. Corp. v. Issacharoff*, 188 Misc. 2d 790 (Sup. Ct. N.Y. Co. 2000) (GBL § 349 claim dismissed where claim unique to the parties);

*Cruz v. Nynex Info Resources*, 263 A.D.2d at 290, the only case cited by defendants for the proposition that in order to show the conduct in question is consumer oriented, “the State must show that the acts or practices complained of are ‘directed to consumers’” (Def. Mem. at 42), states no such thing. *Cruz* simply says that such a showing will satisfy the consumer-oriented standard, not that such a showing is required. Indeed, as the legislative history indicates, and as courts and commentators have uniformly noted, conduct need not be directed at consumers to be actionable under GBL § 349. *See, e.g., Blue Cross and Blue Shield of New Jersey, Inc.*, 344 F.3d at 218; *Feldman*, 210 F. Supp. 2d at 301; *Securiton*, 65 F. 3d at 264. *See also* Moldovan, 48 Brook. L. Rev at 525 - 526.

3. **GBL § 349 AUTHORIZES THE ATTORNEY GENERAL TO RECOVER RESTITUTION FOR ALL OVERPAYMENTS MADE AS A RESULT OF DEFENDANTS’ DECEPTIVE CONDUCT, WHETHER SUCH OVERPAYMENTS WERE MADE BY THE STATE, ACTING ON BEHALF OF ITS CITIZENS, OR BY INDIVIDUAL HEALTH CARE CONSUMERS.**

Defendants’ third contention -- that GBL § 349 does not authorize the State to sue for its own losses -- is, like their preceding argument, contrary to the express language of the statute and its broad remedial purpose.

In fact, GBL § 349(b), the provision that authorizes the Attorney General to bring an action for deceptive practices, contains no limitation on the scope of the relief that may be afforded. To the contrary, this section expressly authorizes the Attorney General to “bring an action in the name and on behalf of the people of the State of New York to enjoin such unlawful acts or practices and to obtain restitution of any moneys or property obtained directly or indirectly by any such unlawful acts or practices.”

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*Fashion Boutique of Short Hills. v. Fendi*, 1992 WL 170559, at \*4 (S.D.N.Y. 1992) (competitor claim for disparagement did not properly present a claim for deceptive practices under GBL § 349 where the gravamen of the plaintiff’s claim was harm to it, not to its customers or the public at large); *Cruz v. Nynex Info. Resources*, 263 A.D.2d 285 (1<sup>st</sup> Dep’t 2000) (no 349 claim where only businesses affected by defendant’s conduct).

Defendants do not cite a single case in support of the proposition that the State cannot receive restitution for its own losses. Indeed, the only case relied on by them is *State v. Princess Prestige Co.*, 42 N.Y.2d 104, 108 (1977), a case which arose under Exec. Law § 63(12) and not under GBL § 349. ("No defense is available under subdivision (b) of section 349 of the General Business Law, inasmuch as this is not a proceeding under article 22-A of that law."). In addition, *Princess Prestige* stands for a proposition directly opposite to that asserted by defendants: that in an action brought by the Attorney General pursuant to his statutory authority to obtain equitable relief on behalf of the public, the court has broad remedial powers to fashion appropriate relief and to direct restitution. *Id.* While *Princess Prestige*, like many of the enforcement actions brought by the Attorney General under GBL § 349 and Exec. Law § 63(12), involves the deception of consumers and thus seeks to obtain relief for consumers, nothing in either statute limits the Court to ordering restitution only for consumers.

Indeed, even in private litigation under GBL § 349(h), courts have repeatedly held that one need not be a consumer to have standing to bring a claim or recover under the statute. As the Second Circuit recently held in *Blue Cross and Blue Shield*, 344 F.3d at 218-219:

[A] plaintiff need neither be a consumer nor be someone standing in the shoes of a consumer to have an actionable claim under Section 349. Thus, 'the critical question...is whether the matter affects the public interest in New York, not whether the suit is brought by a consumer....' [T]he fact that [the plaintiff] was not a consumer of defendants' products does not prevent it from having standing to sue on its own behalf under Section 349.

*See also Securitron*, 65 F.3d at 264 (business that was injured as a result of competitors' deceptive statements to safety regulatory authority could recover under GBL § 349); *Vitolo v Dow Corning*, 166 Misc. 2d 717 (Sup. Ct. N.Y. Co. 1995) (physician had standing to sue silicon breast implant manufacturers under GBL § 349 for injuries that would not have occurred but for manufacturers' failure to disclose the dangers of their breast implants); *In re MTBE Product Litig.*, 175 F. Supp. 2d at 593 (plaintiff well owners could recover under GBL § 349 for conduct that misled all consumers, including plaintiffs, as to the dangers and safety concerns of gasoline containing MTBE).

4. **ALTHOUGH DEFENDANTS' CONDUCT DID, AS ALLEGED IN THE COMPLAINTS, RESULT IN INJURY TO INDIVIDUAL CONSUMERS AS WELL AS TO THE STATE, PROOF OF INJURY IS NOT AN ELEMENT OF A DECEPTIVE PRACTICES CLAIM UNDER GBL § 349(b).**

Defendants' fourth contention – that to assert a claim under GBL § 349, the plaintiff must show that defendants' material deceptive act caused the injury – is plainly incorrect. While injury is a necessary element of a claim brought by private individuals pursuant to GBL § 349(h),<sup>16</sup> injury is not a necessary element of a deceptive practices claim brought by the Attorney General pursuant to GBL § 349(b). *Guggenheimer v. Ginzburg*, 43 N.Y.2d 268, 272-273 (1977) *Accord*, *Goshen v. Mutual Life Insurance Company of New York*, 98 N.Y.2d 314, 324 (2002).

GBL § 349(b) expressly states that the Attorney General can bring an action whenever any person “has engaged in or is about to engage in” deceptive practices. (Emphasis supplied). The statute was intended to provide the Attorney General with the authority to prevent fraud in its incipiency. *Oswego*, 85 N.Y.2d at 25. Proof of injury is not required. *Guggenheimer v. Ginzburg*, 43 N.Y.2d 268, 272-273 (1977) (“To establish such a cause of action it need not be shown that consumers are being or were actually injured.”). *Accord*, *Goshen v. Mutual Life Insurance Company of New York*, 98 N.Y.2d 314, 324. For this reason, the Attorney General may proceed with an action pursuant to GBL § 349 without proof that anyone has been injured and even before the deceptive act is consummated. *See State v. Lipsitz*, 174 Misc. 2d 571, 580 (Sup. Ct. N.Y. Co. 1997) (“the Attorney General's mandate is sufficiently broad that

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<sup>16</sup> In contrast to GBL § 349(b), which authorizes the Attorney General to sue for injunctive relief and restitution, GBL § 349(h) which provides for private damages actions states in relevant part:

In addition to the right of action granted to the attorney general pursuant to this section, *any person who has been injured by reason of any violation of this section* may bring an action in his own name to enjoin such unlawful act or practice, an action to recover his actual damages or fifty dollars, whichever is greater, or both such actions.

(Emphasis supplied).

the Attorney General could commence enforcement actions even if no complaints were to exist"); *State v. Management Transition Resources*, 115 Misc. 2d 489, 491 (Sup. Ct. N.Y. Co. 1982) ("It is not necessary for the Attorney General to await consumer complaints before proceeding. . ."). That direct causation is not required in an action brought by the Attorney General under GBL § 349 is further made clear by the fact that § 349(b) expressly provides for restitution of "any moneys or property *obtained directly or indirectly*" by any defendants' deceptive practices. (Emphasis supplied.)<sup>17</sup>

Even apart from the legal requirements of a claim under GBL § 349(b), defendants' conduct as set forth in the complaints has, in fact, caused substantial harm to infirm and elderly New Yorkers who have been forced to pay Medicare Part B co-payments for cancer and other drugs which are significantly higher than the amounts they would have paid had defendants accurately reported either the true average wholesale prices or the true wholesale acquisition costs on which the published average wholesale prices were based. (Compls. ¶¶ 33 - 34.) State taxpayers have also suffered as a direct result of defendants' alleged deceptive practices by reimbursing pharmacists under the state Medicaid and EPIC programs significantly more than they should have had defendants provided accurate information to the commercial

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<sup>17</sup> Even with respect to private actions under GBL § 349(h), there is ample precedent for the principle that such plaintiffs may sue for indirect injuries. Thus, the district court in an extensive discussion in *Empire Blue Cross and Blue Shield v. Philip Morris USA, Inc.*, 178 F. Supp. 2d at 232-235, held that "businesses and consumers suffering indirect injuries may sue under the statute." *Id.* at 232. Although the Second Circuit in *Blue Cross*, 344 F.3d at 211, subsequently certified the narrow question of whether claims by a third party payer of health care costs seeking to recover the costs of services provided to subscribers as a result of those subscribers being harmed by a defendant's violation of GBL § 349 was too remote to permit suit under GBL § 349(h), *id.* at 221, the court noted that the statute's remedial and deterrent purposes and its deliberate relaxation of common law tort requirements indicated an intent to allow private plaintiffs to recover for indirect injuries. Noting as well the existence of case law supporting this conclusion, the court questioned the soundness of the same cases relied on by defendants herein. (Def. Mem. at 47). The court thus noted that the decision in *Eastern States Health & Welfare Fund v. Philip Morris, Inc.*, 188 Misc. 2d 638 (Sup. Ct. N.Y. Co. 2000) "never discussed Section 349 and it is not even clear from the opinion whether a Section 349 claim was part of that action," while the decision in *A.O. Fox Memorial Hospital v. American Tobacco Co.*, 302 A.D.2d 413 (2d Dep't 2003), "supported its holding by simply citing three cases which did not address Section 349." 344 F.3d at 220.

drug price reporting services. (Compls. ¶ 38.) Soc. Serv. Law § 18 N.Y.C.R.R. § 360-7.7 (Medicaid pays the Medicare coinsurance for individuals eligible for both programs.) As set forth in the complaints, (¶15), defendants are aware that the prices they submit to these reporting services will be used to determine reimbursement and co-payment amounts, yet submit grossly inflated wholesale price data. (Compls. ¶ 22.) No “intervening acts” as characterized by defendants (Def. Mem. at 46) change the fact that but for defendants’ misrepresentations, the public would not have suffered the harms described in the complaints.

**B. The Complaints State A Claim For Repeated and Persistent Fraudulent Conduct Under Exec. Law § 63(12).**

Without citing a single case under Exec. Law § 63(12), defendants argue for dismissal of plaintiffs’ second cause of action for repeated and persistent fraudulent conduct under Exec. Law § 63(12) on the same mistaken grounds as those asserted with respect to the GBL. (Def. Mem. at 48). Having thoroughly misconstrued the elements of a claim under GBL § 349, defendants similarly misinterpret the nature of a claim for fraud under Exec. Law § 63(12).

Exec. Law § 63(12) empowers the Attorney General to seek an injunction, restitution, and damages where any person or business has engaged in repeated fraudulent or illegal acts.<sup>18</sup> Like GBL § 349, Exec. Law § 63(12), the other principal source of the Attorney General’s authority to combat illegal and fraudulent conduct, is to be construed liberally to effectuate its remedial purpose. *See e.g., Princess Prestige Co.*, 42 N.Y.2d at 108; *State v. Maiorano*, 189 A.D.2d 766 (2d Dep’t 1993). The

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<sup>18</sup> “Repeated” fraudulent conduct is defined by the statute to “[i]nclude repetition of any separate and distinct fraudulent act, or conduct which affects more than one person.” *See, e.g., State v. Empyre Inground Pools*, 227 A.D.2d 731, 733 (3d Dep’t 1995). Persistent is defined by statute to include the “continuance or carrying on of any fraudulent or illegal act or conduct.” Executive Law § 63(12).



meaning of fraud under section 63(12) is thus given parallel construction to that of deceptive practices under GBL § 349. *State v. State Christian College*, 76 Misc. 2d at 55.<sup>19</sup>

Section 63(12) broadly defines "fraud" and "fraudulent" as follows:

The word "fraud" or "fraudulent" as used herein shall include any device, scheme or artifice to defraud and any deception, misrepresentation, concealment, suppression, false pretense, false promise or unconscionable contractual provisions.

Like GBL § 349, the judicial interpretation of statutory fraud pursuant to Exec. Law § 63(12) has always been broad, going well beyond that found in the common law. In *People v. Federated Radio Corp.*, 244 N.Y. 33, 38 - 39 (1926), the Court of Appeals, in construing the Martin Act, the statute on which Exec. Law § 63(12) was based, wrote:

In a broad sense the term [fraud] includes all deceitful practices contrary to the plain rules of common honesty...The words 'fraud' or 'fraudulent' in this connection should, therefore, be given a wide meaning so as to include all acts, although not originating in any actual evil design or contrivance to perpetrate fraud or injury upon others, which do by their tendency to deceive or mislead the purchasing public come within the purpose of the law.

In the more than 70 years since the Court articulated this definition of statutory fraud, courts at all levels have followed this broad view of what constitutes fraudulent and deceptive conduct under Exec. Law § 63(12). *State v. Bull Inv.*, 46 A.D.2d 25, 28 (3d Dep't 1974), *appeal denied*, 35 N.Y.2d 647 (1975); *State v. General Motors Corp.*, 120 Misc. 2d 371, 374 (Sup. Ct. N.Y. Co. 1983); *State v. Bevis Industries, Inc.*, 63 Misc. 2d 1088, 1090 (Sup. Ct. N.Y. Co. 1970); *State v. State Christian College*, 76 Misc. 2d at 56. Thus, it is well-settled that, as with GBL § 349, the traditional elements of common law fraud such as reliance, actual deception, knowledge of deception and intent to deceive are not required to establish liability for statutory fraud under Exec. Law § 63(12). *See State v. General Electric Co., Inc.*, 302 A.D.2d 314 (1<sup>st</sup> Dep't 2003); *State v. Apple Health and Sports Club, Ltd.*, 206 A.D.2d 266, 267 (1<sup>st</sup> Dep't 1994),

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<sup>19</sup> Since the persistent or repeated violation of any other statute, including GBL § 349, is actionable under § 63(12), the Attorney General is permitted, as here, to use § 63(12) and § 349 together. *See State v. Feldman*, 210 F. Supp. at 294; *State v. Telehublink*, 301 A.D.2d 1006 (3d Dep't 2003); *Empyre Inground Pools*, 227 A.D.2d at 732; *State v. Allied Marketing Group, Inc.*, 220 A.D.2d 370 (1<sup>st</sup> Dep't 1995).

*appeal denied*, 84 N.Y.2d 1004 (1994); *State v. Ford Motor Co.*, 136 A.D.2d 154, 158 (3d Dep't 1988), *aff'd*, 74 N.Y.2d 495 (1989).

Exec. Law § 63(12) applies to virtually “all business activity” and, contrary to defendants’ contention, is not limited to consumer protection actions. *Feldman*, 210 F. Supp. 2d at 299 (“[D]efendants’ claim that section 63(12) is limited to consumer protection actions is simply incorrect.”). Thus, the Attorney General has used the statute to secure relief for a wide range of cases that are not consumer cases in the narrow sense of the term as used by defendants. *See, e.g., State v. Feldman*, 210 F. Supp. 2d at 300 (action for anti-trust violations); *State v. Mid Hudson Med. Group, P.C.*, 877 F. Supp. 143, 144, 146-47 (S.D.N.Y. 1995) (action on behalf of hearing impaired New Yorkers discriminated against in the provision of medical services); *People v. Lexington Sixty-First Assocs.*, 38 N.Y.2d 588 (1976) (action on behalf of tenants and investors harmed by illegal scheme for cooperative conversion); *State v. Fashion Place Assocs.*, 224 A.D.2d 280 (1<sup>st</sup> Dep’t 1996) (action on behalf of tenants harmed by defendant’s denial of rent-stabilized leases); *State v. Hamilton*, 125 A.D.2d 1000 (4<sup>th</sup> Dep’t 1986) (action on behalf of female employees harmed by sex discrimination); *State v. World Interactive Gaming Corp.*, 185 Misc. 2d 852 (Sup. Ct. N.Y. Co. 1999) (action to enjoin defendants from offering Internet gambling to New Yorkers); *State v. MacDonald*, 69 Misc. 2d 456, 458 (Sup. Ct. N.Y. Co. 1972) (action to enjoin shipping line and ship masters from operating without a license in violation of New York Navigation Law).

Nothing in Exec. Law § 63(12) precludes the Court from awarding restitution for overpayments made by the State as well as consumers. Since § 63(12), like GBL § 349, is to be broadly construed to effectuate the statute’s remedial purposes, an application for relief under the statute is “addressed to the sound judicial discretion of the trial court.” *Princess Prestige*, 42 N.Y.2d at 108; *Scottish American Association, Inc.*, 52 A.D.2d at 528. The courts have wide latitude to establish appropriate restitution procedures in a given case. *Ford Motor Co.*, 136 A.D.2d at 158. Restitution may be granted for all



injured parties, including those “known and unknown” at the time of the order. *Scottish American Association*, 52 A.D.2d at 528.

For the reasons described above, defendants’ reporting of fictitious prices constitutes repeated and persistent fraudulent conduct that is actionable under Exec. Law § 63(12).

**C. The Complaints State a Claim for Repeated and Persistent Illegal Conduct Pursuant to Exec. Law § 63(12) Based on Defendants’ Violations of Penal Law Article 180.**

In addition to fraudulent conduct, Exec. Law 63(12) authorizes the New York State Attorney General to seek “an injunction, restitution and damages against any person who engages in repeated illegal acts.” *State v. Concert Connection, Ltd.*, 211 A.D.2d 310, 313 (2d Dep’t 1995). This provision is “construed quite broadly so that its salutary provisions are applied to all business activity accompanied by repeated acts of illegality.” *People v. MacDonald*, 69 Misc.2d at 458. Thus, the violation of any state, federal or local law or regulation constitutes “illegality” within the meaning of § 63(12) and is actionable thereunder when the violation is persistent or repeated. *See, e.g., Princess Prestige*, 42 N.Y.2d at 106 (violations of the Home Solicitation Act, P.P.L. Art. 10-A); *Empyre Inground Pools*, 227 A.D.2d at 733 (violations of home improvement law); *Ford Motor Co.*, 136 A.D.2d at 154 (violation of New York Lemon Law); *Concert Connection Ltd.*, 211 A.D.2d at 310 (violation of Arts and Cultural Affairs Law § 25.01); *Apple and Health Sports Clubs, Ltd.*, 206 A.D.2d at 267 (1<sup>st</sup> Dep’t 1994) (violations of health club law); *State v. American Motor Club*, 179 A.D.2d 277 (1<sup>st</sup> Dep’t 1992), *appeal dismissed*, 80 N.Y.2d 893 (*violations of Insurance Law*); *State v. Midland Equities*, 117 Misc. 2d 203 (Sup. Ct. N.Y. Co. 1982) (violation of the Judiciary Law). As alleged in the complaints (¶ 36), defendants’ conduct with respect to Medicare drugs sold to and administered by physicians constitutes repeated and persistent commercial bribing that is actionable under Exec. Law § 63(12).

Violations of criminal law likewise are actionable under Executive Law § 63(12). *See, e.g., Freedom Discount Corp. v. Korn*, 28 A.D.2d 517 (1st Dep’t 1967) (violation of Penal Law §§ 1370 and 1371); *State of New York v. World Interactive Gaming Corp.*, 185 Misc.2d 852 (Sup. Ct. N.Y. Co. 1999)

(promoting gambling in violation of New York Penal Law Article 225 and federal Wire and Travel Acts, 18 U.S.C. §§ 1084, 1952, 1953); *State of New York v. ITM*, 52 Misc. 2d 39 ( Sup. Ct. N.Y. Co. 1966) (violation of Penal Law §§ 1370 and 1371); *Wiener v. Abrams*, 119 Misc. 2d 970 (Sup. Ct. N.Y. Co.1983) (violation of Penal Law §180.55); *State of New York v. Colorado State Christian College of Church*, 76 Misc. 2d 50 (Sup. Ct. N.Y. Co. 1975) (violation of Penal Law § 950); *State v. Abortion Info. Agency, Inc.*, 69 Misc. 2d 825 (Sup. Ct. N.Y. Co. 1971), *aff'd*, 37 A.D.2d 142 (1st Dep't 1971), *aff'd*, 30 N.Y.2d 779 (1972) (violation of Education Law §§ 6514 and 6501 which provide for criminal prosecution).

The elements of commercial bribing in New York are simply stated. Penal Law § 180.00 provides that:

A person is guilty of commercial bribing in the second degree when he confers, or offers or agrees to confer, any benefit upon any employee, agent or fiduciary without the consent of the latter's employer or principal, with intent to influence his conduct in relation to his employer's or principal's affairs.

*See also Southmark/Envicon Capital Corp. v. United Airlines, Inc.*, 132 Misc. 2d 586, 589 (Sup. Ct. N.Y. Co. 1986), *aff'd*, 130 A.D.2d 987(1<sup>st</sup> Dep't 1987). The term "benefit" is broadly and explicitly defined as "any gain or advantage to the beneficiary and includes any gain or advantage to a third person pursuant to the desire or consent of the beneficiary." Penal Law § 10.00(17). The provision generally is to be construed "according to the fair import of its terms to promote justice and effect the objects of the law." Penal Law § 5.00. *See also People v. Keyes*, 75 N.Y.2d 343, 348 (1990); *People v. Ditta*, 52 N.Y.2d 657, 660 (1981). Commercial bribery may also give rise to a civil action. *Niagara Mohawk Power Corp. v. Freed*, 265 A.D.2d 938, 939 (4<sup>th</sup> Dep't 1999).

There is no merit to defendants' contention that the State has failed to state a cause of action for repeated illegal conduct based on a violation of Penal Law § 180.00 because physicians have no fiduciary obligation to their patients, or because it is the government reimbursement programs, not defendants, that conferred a benefit on physicians. (Def. Mem. at 49-52.)

The existence of a fiduciary obligation is determined by the relationship of the respective parties:

Whether a fiduciary relationship exists is a matter of fact. . . . At the heart of the fiduciary relationship lies reliance and de facto control and dominance. . . . One acts in a fiduciary capacity when the business with which he or she transacts, or the money or property which he or she handles, is not his or her own or for his or her own benefit, but for the benefit of another person, as to whom he or she stands in a relation implying and necessitating great confidence and trust on the one part and a high degree of good faith on the other part. . . . I instruct you that a fiduciary owes a duty of honest services to his customer, including a duty to disclose all material facts concerning the transaction entrusted to it.

*U.S. v. Szur*, 289 F.3d 200, 210 (2d Cir. 2002). There can be little doubt that the traditional relationship of physicians to patients – involving profound reliance, judgment exercised for another’s benefit, trust and “a high degree of good faith” – meets this standard. In fact, the courts have repeatedly held that doctors have a fiduciary obligation to their patients:

Liability may arise where a duty obtains, if one speaks at all, to provide truthful information. Thus, we conclude that because the defendant treating physician stands in a relationship of confidence and trust to his patient, he owed plaintiffs in this case a duty to speak the truth about her medical condition. While no issue of breach of confidentiality of the physician-patient privilege remains in this case, some context is still relevant. In New York, the special relationship akin to a fiduciary bond, which exists between the physician and patient, is reflected in CPLR 4504.

*Aufrichtig v. Lowell*, 85 N.Y.2d 540, 546 (1995); *Ross v. Community General Hosp.*, 150 A.D.2d 838, 841 (3d Dep’t 1989) (“...the fiduciary relationship between physician and patient, in which confidence is normally reposed in the integrity of one’s physician...”). *Accord*, *Swayze v. McNeil Laboratories, Inc.*, 807 F.2d 464, 471 (5<sup>th</sup> Cir. 1987); *Nardone v. Reynolds*, 538 F.2d 1131, 1135 (5<sup>th</sup> Cir. 1976); *U.S. v. Willis*, 778 F. Supp. 205, 209 (S.D.N.Y. 1991). The cases relied on by defendants, *Arias v. Flushing Hosp. Med. Center*, 300 A.D.2d 610 (2d Dep’t 2002) and *Anderson v. Lamaute*, 306 A.D.2d 232, 233 (2d Dep’t 2003), are not to the contrary. Neither involve doctors being offered financial benefits to elect a particular course of medical treatment, but rather are simply medical malpractice actions in which the court held that there was no departure from the accepted standard of care.

Defendants’ remaining argument for dismissal of this cause of action is yet another unavailing incantation of their untenable “government knowledge” defense. Despite their fictitious reporting of wholesale prices and their marketing of the spread to physicians who purchased their drugs, defendants

contend that any benefit that was conferred on physicians for the purpose of influencing the drugs they prescribed was conferred, not by defendants, but by the federal government. (Def. Mem. at 52-53.) This argument, for which defendants offer no support,<sup>20</sup> fails for all the reasons discussed above. See Point I above. As the *Lupron MDL* court stated, 2003 WL at \*15-16:

The suggestion that Congress would deliberately condone a bribery scheme using public funds to enrich drug manufacturers and physicians is, to say the least, unusual. [fn 15] If this were Congress's purpose, one would think it would have been more effective to simply bribe doctors directly without offering drug companies a cut. On the larger issue, I do not understand why a doctor, who is being paid to administer a drug to a patient, is entitled to earn a profit on the drug he injects. A doctor does not earn a commission (or so one hopes) on a drug that he prescribes.

Commercial bribery statutes have been recognized as particularly appropriate means for addressing prescription drug price manipulation and physicians' receipt of payments that affect their professional judgment. *Pharmacare v. Caremark*, 965 F. Supp. 1411, 1423 (D. Haw. 1996) (involving a claim of commercial bribery where doctors, acting as fiduciaries of patients, were bribed by plaintiff's competitor). As reflected in a 1994 OIG Fraud Alert:

Traditionally, physicians and pharmacists have been trusted to provide treatments and recommend products in the best interest of the patient. In an era of aggressive drug marketing, however, patients may now be using prescription drug items, unaware that their physician or pharmacist is being compensated for promoting the selection of a specific product.... A marketing program that is illegal under the anti-kickback statute may pose a danger to patients because the offering or payment of remuneration may interfere with a physician's judgment in determining the most appropriate treatment for a patient.

OIG Fraud Alert, 59 Fed. Reg 65372 (1994). (Fire. Aff. Ex 6.)

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<sup>20</sup> The only case cited by defendants in support of this proposition, *People v. Teitelbaum*, 138 A.D.2d 647, 649 (1<sup>st</sup> Dep't 1988), is not on point. *Teitelbaum* did not involve commercial bribery, but rather the conviction of two police officers for receiving a bribe. Not only did the court affirm the convictions, but contrary to defendants' characterization, the court did not affirm the dismissal of an alleged accomplice to commercial bribery (Def. Mem. at 53). It simply affirmed the refusal of the trial court to charge the jury that certain of the witnesses were accomplices under the law.

The complaints allege that defendants conferred a benefit upon physicians, who have a fiduciary obligation to their patients; without the patients' consent and for the purpose of inducing the physicians to prescribe defendants' products. (Compls. ¶ 36.) This claim plainly states a cause of action for a violation of the Penal Law proscription against commercial bribery and thus constitutes repeated and persistent illegal conduct under Exec. Law § 63(12).

**D. The Complaints State a Claim for Repeated and Persistent Illegal Conduct Pursuant to Exec. Law § 63(12) Based on Defendants' Violations of 18 N.Y.C.R.R. § 515.2, the Medicaid Anti-kickback Regulation.**

The State's fourth cause of action charges defendants with engaging in unacceptable practices in violation of the Medicaid Program Anti-kickback regulation, 18 N.Y.C.R.R. § 515.2. Under this regulation, unless a "discount or reduction in price is disclosed to the client and the department and reflected in a claim, or a payment is made pursuant to a valid employer-employee relationship," it is an unacceptable practice to offer or pay

either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the program.

18 N.Y.C.R.R. § 515.2(b)(5)(iv).<sup>21</sup>

This regulation parallels the federal anti-kickback prohibition, 42 U.S.C. § 1320a-7b, and the considerable case law interpreting the comparable federal statute is indicative of the breadth of the state regulation. A person who offers or pays remuneration to another person violates the federal anti-kickback statute even if only *one* of the purposes of the offer or payment is to induce Medicare or Medicaid patient referrals. *U.S. v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); *U.S. v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985);

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<sup>21</sup> This regulation is drawn more broadly than the Soc. Serv. Law § 366-d anti-kickback statute, as exemplified by its inclusive definition of "payment" and its incorporation of "recommending any medical care, services or supplies" as illicit *quid pro quo* conduct. Also, unlike Social Services Law § 366-d, the regulation encompasses entities that are not Medicaid providers. 18 N.Y.C.R.R. § 515.2(b)(18).

see also *U.S. v. Bay State Ambulance and Hospital Rental Service, Inc.*, 874 F.2d 20, 30 (1<sup>st</sup> Cir. 1989).

“Remuneration” has been defined even more broadly than “kickback” and encompasses any money received in exchange for a proscribed referral. *U.S. v. Mittal*, 1999 WL 461293 (S.D.N.Y. Jul. 07, 1999). Similarly, the state regulation prohibits any “payment” in return for purchasing, ordering or recommending any medical treatment, service or supplies.

Defendants fraudulently create and market the spread on their drugs to New York pharmacists who are Medicaid providers in order to induce them to recommend defendants’ drugs to Medicaid recipients and their physicians. ) Compls. ¶ 30.) The enhanced reimbursements provided to pharmacists as a result of defendants’ fraudulent acts are the *quid pro quo* for recommending defendants’ drugs, and, together with those providers who accept this offer, intentionally causes Medicaid to pay the falsely overstated prices. Accordingly, defendants’ conduct in inducing Medicaid providers to purchase and prescribe their products by manipulating government pricing systems to generate enhanced reimbursements falls within the clear ambit of 18 N.Y.C.R.R. § 515.2(b)(5). It constitutes the offering of indirect payment from Medicaid in return for providers ordering and recommending the defendants’ products.

Defendants challenge this cause of action on two bases: that the conduct only relates to Medicaid pharmacists and inducing pharmacists “makes no economic sense” because doctors, not pharmacists, decide which drugs are prescribed (Def. Mem. at 55) and, in yet another iteration of the “government knowledge” defense, that the information provided to the EPIC program afforded the State an opportunity to discover what defendants were doing (Def. Mem. at 55 - 56). Neither states a valid objection.

First, defendants’ blanket assertion that the alleged conduct, marketing the spread, makes no sense is not a basis for dismissal. There is nothing in Exec. Law § 63(12) or in the Medicaid anti-kickback regulation that allows parties to violate the law based on their assessment of its wisdom. Moreover, what defendants describe as “senseless” has actually been identified by federal regulators as an area of special concern. In the 1994 Special Fraud Alert quoted above, the OIG noted that aggressive marketing schemes



could result in patients using prescription drugs unaware that their physician or pharmacist is being compensated for promoting the selection of that drug. 59 Fed. Reg. 65372. The OIG cited as one example a product conversion program which had resulted in 96,000 brand-name conversions after one drug company offered a cash award to pharmacies for each time they changed a drug prescription to the company's product. The OIG concluded that inducing pharmacies to help persuade physicians, who were unaware of the pharmacies' financial interest, to change prescriptions implicated the anti-kickback law.

If one purpose of any of these marketing schemes is to induce the provision of a prescription drug item reimbursable by Medicaid, then the criminal anti-kickback statute is implicated. There is no statutory exception or "safe harbor" to protect such activities. Thus a physician, pharmacy or other practitioner or supplier receiving payment under these activities may be subject to criminal prosecution and exclusion from participation in the Medicare and Medicaid programs

*Id.* at 65376.

The OIG further noted that anti-kickback investigations may be warranted where "one or more of the following features is present in prescription drug marketing activities":

Materials which offer cash or other benefits to pharmacists (or others in a position to recommend prescription drug products) in exchange for performing marketing tasks in the course of pharmacy practice related to Medicare or Medicaid. . .

Any payment, including cash or other benefit, given to a patient, provider or supplier for changing a prescription, or recommending or requesting such a change, from one product to another.

*Id.* at 65376.

"Marketing the spread" through the inflation of reported average wholesale prices has, in particular, been recognized as one of the practices that runs afoul of anti-kickback laws.

If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated . . . Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product....The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute. Active marketing of the spread includes, for example,

sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product.

2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23737. The same guidance, recognizes pharmacists as “entities in a position to generate federal health care business” and identifies payments to cover the costs of “converting” from a competitor’s product as prohibited remuneration, *id.* at 23734, 23736.

Defendants’ remaining argument is that information from which true pricing data could be derived has been provided to the EPIC Program, and that the State could have availed itself of this information to negate defendants’ price misrepresentations. This ignores the fact that the Average Manufacturers Price and Best Price data reported to EPIC are required to be kept confidential (Aff. of Stephen C. Abbott) and that, even if the State did “know” defendants’ true wholesale prices, such knowledge would not absolve defendants of their responsibility for financially influencing prescription patterns. The anti-kickback regulation prohibits offering inducements to providers to affect their medical judgments, and the State’s awareness, *vel non*, of how much profit a pharmacy could make for a given drug, is irrelevant to the analysis. The claim is properly pleaded and defendants’ motion should be denied.

**E. The Complaints State a Claim for Repeated and Persistent Illegal Conduct Pursuant to Exec. Law § 63(12) Based on Defendants’ Violations of Soc. Serv. Law § 145-b.**

The State’s Fifth Cause of Action charges defendants with violating Soc. Serv. Law § 145-b.

Section 145-b states in relevant part:

(a) It shall be unlawful for any person, firm or corporation knowingly by means of a false statement or representation... *or other fraudulent scheme or device*, on behalf of himself *or others*, to attempt to obtain or to obtain payment from public funds for services or supplies furnished or purportedly furnished pursuant to this chapter.

(b) For purposes of this section, “statement or representation” includes, but is not limited to:... an acknowledgment, certification, claim, ratification *or report of data which serves as the basis for a claim or a rate of payment, financial information whether in a cost report or otherwise*... [Emphasis added]

(c) For purposes of this section, a person, firm or corporation has attempted to obtain or has obtained public funds *when any portion of the funds from which payment was attempted or obtained are public funds*... [Emphasis added]



As is evident from this statutory language, section 145-b affords the State broad authority to recover funds from individuals or entities whose fraudulent activity causes increased costs to State-funded programs, including Medicaid. As alleged in the complaints (§ 28), defendants violated section 145-b by falsely reporting inflated wholesale price data that served as the basis for Medicaid and EPIC reimbursement and thereby obtaining inflated Medicaid payments for pharmacies. While defendants argue that the statute is limited to those who actually submit false claims for health services to the state (Def. Mem. at 59), no such restriction exists. Indeed, the statute's reference to "false statement...or other fraudulent scheme or device" belies the existence of such a restriction. Likewise, the expansive definition of "statement or representation" in paragraph (b), by its express terms, goes far beyond a claim to include a "report of data which serves as the basis for a claim or a rate of payment," and "financial information whether in a cost report or otherwise."

Finally, defendants' attempt to characterize their reporting of false prices to the compendia which publish the information relied on by the government to set reimbursement levels as too "tenuous" to fit within the conduct prohibited by section 145-b again ignores their direct role in the reimbursement process. But for defendants' submission of false price data, there would be no overpayments for drugs under EPIC or Medicaid. Contrary to defendants' contention, neither the health care providers who bill at the rate the defendants cause to be set or the government agencies that rely on defendants' inflated price information can be deemed "intervening" causes which absolve defendant for the violation of the law. *Kuriansky v. Kermani* (Sup. Ct. N.Y. Co. 1998) (unreported decision) (rejecting defendant's contention that he was not liable under Social Services Law § 145-b since pharmacies, not he, received the Medicaid payments, noting that "[T]he State loses the same amount of money, and the Medicaid system suffers the same level of abuse, whether the payments are received by the perpetrator of the fraud or by a third party.")

**POINT IV****THE STATE HAS PLEADED ITS CASE  
WITH SUFFICIENT PARTICULARITY.****A. CPLR 3016 Does Not Apply to the State's Claims.**

The State has pleaded its case with more than sufficient detail. CPLR § 3013 simply requires that the complaint give "notice of the transactions, occurrences or series of transactions or occurrences, intended to be proved and the material elements of each cause of action or defense." The complaints need only advise the defendants and the court of the State's claims, *Foley v. D'Agostino*, 21 A.D.2d 60, 62, (1<sup>st</sup> Dep't 1964), and to set forth the material elements of each cause of action. *Shapolsky v. Shapolsky*, 22 A.D.2d 91 (1<sup>st</sup> Dep't 1964).

Defendants, however, assert that each of the State's causes of action must additionally meet the requirements of CPLR 3016(b), which states that the "circumstances constituting the wrong shall be stated in detail" for actions based on fraud or mistake. This provision applies only to actions grounded in common law fraud. *Joannou v. Blue Ridge Ins. Co.*, 289 A.D.2d 531 (2<sup>d</sup> Dep't 2001). *See also* *Petitt v. Celebrity Cruises, Inc.*, 153 F. Supp. 2d 240, 265 (S.D.N.Y. 2001); *Hedaya Brothers, Inc. v. FDIC*, 799 F. Supp. 13 (E.D.N.Y. 1992).<sup>22</sup> The State's claims do not share the elements of common law fraud. (Compls. ¶¶ 39-51.)

As discussed in Point III above, scienter, bad faith, intent to defraud and detrimental reliance are not elements of the State's Exec. Law § 63(12) and GBL § 349 claims. Because Rule 3016(b) was only intended to apply to claims based in common law fraud, its requirements do not apply to the State's broader claims under GBL § 349 and Exec. Law § 63(12). *Joannou v. Blue Ridge Ins. Co.*, 289 A.D.2d at 531. *See also* *Banks v. Consumer Home Mortg, Inc.*, 2003 WL 21251584, at \*6 (E.D.N.Y. Mar. 28, 2003)

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<sup>22</sup>While cases under F.R.C.P. 9(b), the federal rule regarding particularity in claims alleging fraud, can be instructive in interpreting CPLR 3016(b), state law requirements with respect to pleading and particularity tend to be even more relaxed than those under federal law. Siegel, N.Y. Practice § 631 (3d ed.).

("[B]ecause Section 349 does not require proof of intent to deceive or justifiable reliance, courts generally hold that Rule 9(b) does not apply to section 349 claims."); *Hedaya Brothers v. FDIC*, 799 F. Supp. at 13 (allegations of fraud are not required in section 349 actions and therefore not subject to Rule 9(b) review); *Petitt v. Celebrity Cruises*, 153 F. Supp. 2d 240, 265 (S.D.N.Y. 2001) (Rule 9(b) does not apply to consumer protection claims).

In *John P. Villano Inc. v. CBS, Inc.*, 176 F.R.D. 130, 131 (S.D.N.Y. 1997), the court rejected the defendant's contention that the plaintiff was required to plead its claim of false advertising with particularity, a conclusion equally applicable to the State's consumer protection claims here. The court explained:

[N]othing in the language or history of Rule 9(b) suggests that it is intended to apply, willy-nilly, to every statutory tort that includes an element of false statement. No matter how parsed, a claim of false advertising . . . is not identical to a claim of fraud. Fraud requires, not just the making of a statement known to be false, but also, inter alia, a specific intent to harm the victim and defraud him of his money or property. *Citations omitted*. That is why Rule 9(b) has been interpreted to require, not just a specification of the alleged misrepresentations, but also a particularization of the facts giving rise to a strong inference that defendant acted with fraudulent intent. *Citations omitted*. By contrast, no fraudulent intent . . . is required under 15 U.S.C. § 1125.

Other jurisdictions agree and do not require heightened pleading for claims of deceptive practices. *E.g., Brady v. Publisher Clearing House*, 787 A.2d 111 (Del. 2001) (deceptive trade practice and consumer fraud claims were not sufficiently analogous to common law fraud to justify heightened pleading); *Leake v. Sunbelt Limited of Raleigh*, 93 N.C. App. 199, (1989) (because intent is irrelevant to a consumer protection claim, plaintiffs need not show fraud and therefore they were not subject to Rule 9(b)).

Fraud is likewise not an element of the State's commercial bribery claim and, therefore, does not need to be pleaded with particularity. *Cougar Audio, Inc. v. Reich*, No. 99 Civ. 4498 LBS, 2000 WL 420546 at 7 (S.D.N.Y. 2000) (particularity not required for commercial bribery because predicate acts do not include fraud). The fourth and fifth claims alleging Medicaid kickbacks and violations of the Social Services Law also do not include the elements of common law fraud.

**B. Even if CPLR 3016 Applies to the State's Claims, the State Has Met its Requirements.**

Assuming CPLR 3016(b) applies to the State's claims, it has pleaded all of its claims with sufficient particularity to meet this Rule's standard. Like CPLR § 3013, CPLR 3016(b) simply requires a plaintiff to set forth each element of its claims. CPLR 3016(b) is no more than a directive that the transactions constituting the wrong be pleaded in sufficient detail to give notice to defendants. *Foley*, 21 A.D.2d at 64. Because the State's complaints provide defendants with notice of its claims and set forth their material elements, they satisfy CPLR 3016(b) as well as Section 3013. *Id.*

In *SEC v. Feminella*, 947 F. Supp. 722, 733 (S.D.N.Y. 1996), the court held that the plaintiff satisfied pleading requirements for pleading securities fraud with particularity, although the complaint alleged only 33 instances of excessive markup, in a scheme that lasted five years, and did not provide further details for each incident, like prices or the size of the markup. The court noted the reasons behind Rule 9(b), as with CPLR 3016(b), were to give a defendant notice of the claim, protect a defendant from harm to his reputation, and reduce the number of strike suits. *Id.* See also *Lupron* MDL, 2003 WL 22839966 at \*11. The complaint gave the defendant reasonable notice of the claim and the grounds on which it was based, and therefore satisfied the main purposes of the particularity requirement. *SEC v. Feminella*, 947 F.Supp at 733. The court concluded that to require the plaintiffs to detail every transaction "by date, amount and markup would contravene the requirements of Rule 8(a) [parallel to Section 3013], while not furthering the purpose behind Rule 9(b)." *Id.*

Here, the State's complaints provide reasonable notice to defendants and plead the material elements of each claim with sufficient particularity: Each complaint describes a uniform deceptive practice that each defendant applies to the drugs with a manipulated average wholesale price, a list exclusively within each defendant's knowledge. Each defendant's pattern of deceptive conduct consists of the following: (1) Defendants report to price compendia for each of their drugs an average wholesale price, or a price that determines published average wholesale price, and defendants know precisely how

the price compendia go from the number defendants report to the average wholesale price the compendia publish. (Av & GSK Compls. ¶¶ 15-18, Pharm. Compl. ¶¶ 15-17.) (2) The amounts defendants report to the price compendia are inflated above the actual acquisition cost at the relevant point in the distribution chain. (Av & GSK Compls. ¶ 22, Pharm. Compl. ¶ 21.) (3) Defendants know that the average wholesale prices the price compendia publish, which are based on defendants' reports, are used to calculate reimbursement for drugs covered under the Medicare, Medicaid and EPIC programs and, as a result, the reimbursement amounts exceed the amount allowed by the health care program, improperly increasing the amounts paid by the health care programs, Medicare beneficiaries and EPIC participants. (Av. & GSK Compls. ¶¶ 20 -34; Pharm. Compl. ¶¶ 19-34.) The State then provides specific examples of drugs with inflated published average wholesale prices as compared to catalog prices. (Av. & GSK Compls. ¶ 25, Pharm. Compl. ¶¶ 24 - 25.)

Providing defendants with reasonable notice does not require a recital of every drug and every detail regarding the pricing of the drugs, particularly where that information is solely within the knowledge and control of the defendants. New York courts have long recognized that less particular pleading will meet the standards of CPLR 3016(b) when the information sought is within the defendants' knowledge and not the plaintiff's. *Corcoran v. America Plan Corp.*, No. CV 86 1729, 1987 WL 4448 at \*5 n. 4 (E.D.N.Y. 1987) (citing *Jered Contracting Corp v. N.Y.C. Transit Authority*, 22 N.Y.2d 187 (1968)). As the Court of Appeals has stated, CPLR 3016(b):

requires only that the misconduct complained of be set forth in sufficient detail to clearly inform a defendant with respect to the incidents complained of and is not to be interpreted so strictly as to prevent an otherwise valid cause of action in situations where it may be 'impossible to state in detail the circumstances constituting a fraud'.

*Lanzi v. Brooks*, 43 N.Y.2d 778, 780, (1977) (quoting *Jered Contracting Corp. v. N.Y.C. Transit Auth.*, 22 N.Y.2d 187 (1968)). See also Siegel, *New York Practice*, § 216 (Westlaw 2003); *United States ex rel. Downy v. Corning, Inc.*, 118 F. Supp.2d 1160, 1172-1173 (D.N.M. 2000) (allowing pleading of general scheme of fraud where information concerning individual instances could be sought during discovery).

The State provided a few examples of inflated published average wholesale prices from a 2001 OIG report. The State could not generalize from this information to all of a defendant's drugs because of the small number of drugs discussed in this report and the wide variation of inflation rates reported in these documents, even among a defendant's products. OIG, "Medicare Reimbursement of Prescription Drugs," OEL-03-00-00310 (2001), at Appendix E (see 10 *supra*, identifying some of defendants' drugs). (Fire. Aff. Ex. 16.)

Defendants Aventis and GSK complain that they were not given notice of the "pricing terms" that the State alleges they report to pricing compendia which serve as the basis for published average wholesale price. But this information is solely in the hands of the defendants and the pricing compendia. Additionally, defendants' practices effectively, or in some cases intentionally, conceal providers' actual acquisition costs. (Av. & GSK Compls. ¶ 25; Pharm. Compl. ¶ 24.) Defendants use a multitude of phrases to represent the same prices, obscuring the exact labels defendants assign to the pricing information they report.<sup>23</sup> Before discovery commences -- currently stayed by defendants' pending motions -- it is impossible for the State to meet the standard posited by the defendants of stating the providers' acquisition cost for every one of defendants' drugs for which they have inflated the average wholesale price, especially when defendants conceal the true acquisition costs. Especially in such circumstances, the courts do not hold a plaintiff to an impossible pleading standard.

The State's complaints fulfill the purpose of CPLR 3016(b), and any deficiencies are attributable to defendants' practices that conceal health care providers' real acquisition costs for drugs. The complaints, therefore, meet the heightened pleading requirement to the extent, if any, it applies.

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<sup>23</sup>If required to replead, the State would allege that defendants use a variety of price concessions to conceal the price health care providers actually pay for drugs, including discounts, after-purchase credits, rebates, contract prices, chargeback arrangements, unrestricted educational grants and free goods offers. The State would further allege that defendants use a variety of labels for the same price. For example, at times list price, wholesale acquisition cost and net wholesale price have all meant the same thing.

**C. If this Court Rules That More Particularity Is Required, Dismissal Is Not an Appropriate Sanction.**

If the court determines that the State's complaints have not been pleaded with sufficient particularity, the State should be permitted to replead after conducting discovery. "[I]f a material element has been omitted, the usual result is that the party is given permission to replead after conducting discovery. A truly dispositive result . . . typically occurs only when the missing element does not exist, 'not when there has merely been a failure to plead it.'" *Sinacore v. State* 176 Misc. 2d 1, 4 (Ct. Claims 1998), quoting Siegel, *Practice Commentary, McKinney's Consolidated Laws of New York*, Book 7B, CPLR C:3013:3, p 723.<sup>24</sup>

Coupled with this principle is the directive found in CPLR 3026 that, "pleadings shall be liberally construed. Defects shall be ignored if a substantial right of a party is not prejudiced." Thus, a party will not be required even to amend a pleading unless failing to do so causes the opposing party some prejudice, and a more drastic remedy for a deficient pleading is inappropriate if amending the pleading will cure the prejudice. Siegel, *Practice Commentary, McKinney's Consolidated Laws of New York*, CPLR C:3026.1 In the *Lupron* MDL, for example, the court allowed plaintiffs an opportunity to conduct discovery to rectify any deficiencies in the particularity of their allegations of mail and wire fraud. 2003 WL 22839966, at \*10-11. See also *Kaufman v. Cohen*, 307 A.D.2d 113 (2003) (fraud allegations satisfied particularity rule where dismissal motions prevented plaintiffs from obtaining discovery on issues of knowledge and intent). Dismissal for lack of detailed pleading is not appropriate in the instant case.

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<sup>24</sup>In the litigation before Judge Saris that defendants cite (Def. Mem. at 34), plaintiffs were permitted to file amended pleadings. *In Re Pharm. Indus. MDL*, 263 F. Supp. 2d at 194.



CONCLUSION

For the reasons set forth above, the Court should deny defendants' motion to dismiss in its entirety.

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